K113320 (pg 1/2)

Exactech® Novation® Element Press-Fit Femoral Stem
Special 510(k) – 510(k) Summary of Safety and Effectiveness

MAR 16 2012

Sponsor: Exactech® Inc.
2320 N.W. 66th Court
Gainesville, FL 32653

Phone: (352) 377-1140
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FDA Establishment Number 1038671

Contact: Vladislava Zaitseva
Regulatory Affairs Specialist

Date: December 21, 2011

Trade or Proprietary or Model Name(s):
Exactech® Novation® Element Press-Fit Femoral Stem

Common Name:
Press-Fit Femoral Stem component

Classification Name:

- Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calicum-Phosphate (21 CFR Section 888.3353, Class II, Product Code MEH)

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K080980	Novation Element Press-Fit Femoral Stem	Exactech, Inc

Indications for Use:
All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

- Cemented femoral stems and cemented acetabular cups are intended for cemented fixation only.
- Press-fit femoral stems and acetabular cups are intended for press-fit fixation.
- Femoral heads and endoprostheses are intended for use in cemented and press-fit applications.

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Device Description:
The proposed Exactech Novation Element Press-Fit Femoral Stems are a modification of the Exactech Novation Element Press-Fit Femoral Stems cleared through premarket notification #K080980.

The predicate and proposed devices have the same intended use and the same basic fundamental scientific technology.

The modified devices share the following similarities with predicate devices:

- The same design features (e.g. stem geometry, femoral head taper design, stem insertion feature)
- The same materials (titanium alloy, hydroxyapatite coating)
- The same shelf life (5 years), and
- Are packaged and sterilized using the same materials and processes (gamma radiation sterilization to a sterility assurance level of 10^{-6}).

This submission proposes expanding the scope of Novation Element femoral stems by adding new components with modified neck geometry and adding alternative coating suppliers.

Substantial Equivalence Conclusion:
The following engineering analyses were conducted to demonstrate substantial equivalence of the proposed device to the predicate Novation Element Press-Fit Femoral Stems:

- An engineering evaluation to determine that the geometric features of the proposed device correspond to the anatomical features of the femur.
- Mechanical testing to confirm that the proposed device, under worst case conditions, has fatigue strength equivalent to other comparable legally marketed femoral stems.
- A comparison of the HA coating characterization information of predicate and proposed devices as outlined in the FDA guidance document "*510(K) Information Needed for Hydroxyapatite Coated Orthopedic Implants*".

In addition to the design similarities listed above, the results demonstrate that the proposed device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 16 2012

Exactech, Inc.
% Ms. Vladislava Zaitseva
Regulatory Affairs Specialist
2320 N.W. 66th Court
Gainesville, FL 32653

Re: K113320
Trade/Device Name: Exactech® Novation® Element Press-Fit Femoral Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: MEH
Dated: January 24, 2012
Received: January 25, 2012

Dear Ms. Zaitseva:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Novation® Element Press-Fit Femoral Stem
Special 510(k) – Indications for Use

510(k) Number: K113320 (pg 1/1)

Device Name: Exactech® Novation® Element Press-Fit Femoral Stem

INDICATIONS

All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

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Prescription Use ___X___ **and/or** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113320